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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,500	06/04/2001	John E. Ware	QMET-201	5112
24972 7590 02/11/2008 FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198				
EXAMINER				
LE, LINH GIANG				
ART UNIT		PAPER NUMBER		
3626				
MAIL DATE		DELIVERY MODE		
02/11/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/873,500

Applicant(s)

WARE ET AL.

Examiner

MICHELLE LE

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-10, 12-15, 17-23, 25-27 and 29-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10, 12-15, 17-23, 25-27, and 29-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Notice to Applicant

1. This communication is in response to Remarks filed by Applicant 11/5/07.

Claims 1-6, 8-10, 12-15, 17-23, 25-27, and 29-45 remain pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6, 8-23, 25-27, and 29-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ware et al. (Ware, Jr., John E., Jakob Bjorner, and Mark Kosinski, Dynamic Health Assessments: The Search for More Practical and More Precise Outcomes Measures, The Quality of Life Newsletter, January 1999-April 1999), in view of Lewis (5,059,127).

4. As per claim 1, Ware teaches a method of assessing the health status or health care of a patient, comprising the steps of:
generating a customized test, based on the patient's characteristics and one or

more health domains selected by a patient or a health care provider, said test having a plurality of questions for said patient in accordance with said selected health domains (Ware; pg. 11, col. 2-3; pg. 12, cols 1-3); administering said test by providing one question at a time to said patient; and after each question (Ware; pg. 12, Col.1); evaluating answers provided by said patient to administered questions to estimate a score and a confidence level in the accuracy of said estimated score (Ware; pg. 11, col. 3, par. 2; pg. 12 Col.1-2; pg. 13 Col. 1-2;)

Ware does not expressly teach:

varying a threshold as a function of said estimated score; and dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside a said threshold.

As per the recitation of "the threshold varying as a function of the estimated Score," Ware discloses the following steps in Figure 3: step 3) re-estimating the score, step 4) re-estimating the confidence interval, step 5) determining whether a stopping rule is satisfied and determining whether the score has been estimated within a preset standard of precision based on the confidence interval, wherein once the precision standard is met, the computer either begins assessing the next concept or ends the battery (considered to be a form of "threshold"), wherein the precision standard based on the confidence interval (i.e., the threshold) is set based on each patient's score (see page 12, col. 1-2). Note, Ware's discussion of where the preset standard of precision is +/-

5.4 for the lowest scoring patients, where these patients scored near or below an established cutoff point used in screening patients for psychiatric disorders.

Note, Ware discloses that the standard of precision was relaxed to ± 7.9 or less for patients at or above the 90th percentile. (See page 12, col. 1 bottom to top of col. 2). From this disclosure that Ware teaches that the threshold (i.e., precision standard based on the confidence interval) varies as a function of the estimated score.

Furthermore, Lewis teaches a similar concept. In particular, Lewis teaches both random and adaptive testlet selections are well known in the art (Lewis; Col. 6, "Random vs. Optimum Selection"). Lewis teaches that the method of assigning variable threshold variables to particular testlets. It would have been obvious to add these features to the teachings of Ware with the motivation of balancing the goals of classification accuracy and test efficiency (Lewis; Col. 3, lines 25-31).

5. As per claim 2, Ware teaches further comprising the step of generating a report regarding the health status of said patient (Ware; pg. 12, col. 3, par.2).

6. As per claim 3, Ware teaches wherein said domain is a condition experienced or perceived by said patient (Ware; pg. 12, Col. 3, para. 1-2).

7. As per claim 4, Ware teaches wherein the step of dynamically modifying includes the step of ranking said plurality of questions in accordance with said estimated score; and selecting a question from said plurality of questions based on said ranking that has not been administered to said patient (Ware; pg. 12, col. 1).

8. As per claim 5, Ware teaches wherein the step of selecting comprises selecting a highest rank question (Ware; pg. 12, col. 1).

9. As per claim 6, Ware teaches wherein the step of dynamically modifying includes the step of terminating said administration of said test if it is determined that said estimated confidence level is within said threshold (Ware; pg. 12, col. 1, para. 2-3).

10. As per claim 8, Ware does not expressly teach wherein the step of generating selects said questions for said domain from a database having questions and answers pertaining to a plurality of domains.

However this feature is well known in the art as evidenced by Lewis. In particular, Lewis teaches that a mastery testing procedure called the "Item Response Theory" (IRT) was well known in the art (Lewis; Col. 1, line 63 to Col. 10, line 7). The IRT guides the selection of questions or items for inclusion in an examination. Furthermore, the IRT is used to determine the number of test items answered correctly or incorrectly (Lewis; Col. 3, lines 25-55). It would have been

obvious to add these features to the Ware teachings with the motivation of balancing the goals of classification accuracy and test efficiency (Lewis; Col. 3, lines 25-31).

11. As per claim 9, Ware teaches wherein the step of administering includes the step of providing a list of possible answers for each question to said patient (Ware; Col. Pg. 13, Col.1-2).

12. As per claim 10, Ware teaches wherein the step of estimating includes the step of statistically analyzing said answers provided by said patient for errors or consistency (Ware; pg. 13, Col. 1-2).

13. As per claim 12, Ware does not expressly teach wherein the step of estimating includes the step of statistically analyzing said answers provided by said patient for estimating non-responsive answers to said test.

However this feature is well known in the art as evidenced by Lewis. In particular, Lewis teaches that a mastery testing procedure called the "Item Response Theory" (IRT) was well known in the art (Lewis; Col. 1, line 63 to Col. 10, line 7). The IRT guides the selection of questions or items for inclusion in an examination. Furthermore, the IRT is used to determine the number of test items answered correctly or incorrectly (Lewis; Col. 3, lines 25-55). It would have been obvious to add these features to the Ware teachings with the motivation of

balancing the goals of classification accuracy and test efficiency (Lewis; Col. 3, lines 25-31).

14. As per claim 13, Ware teaches wherein the step of reporting includes the step of comparing said answers provided by said patient with answers provided by other patients in said domain (Ware; Pg. 12, Col. 1-2 and Pg. 13, Col.1-2).

15. As per claim 14, Ware teaches administering includes the step of administering said test to said patients over a network, wherein said network is one of the following: an Internet, an intranet, a telephone network, and a wireless network (Ware; Pg. 12, Col. 3, par. 1-2).

16. As per claim 15, Ware teaches wherein the step of generating reports includes the step of generating said report over a network (Ware; Pg. 12, Col. 3, par. 1-2).

17. As per claim 17, Ware teaches wherein said domain includes at least one of the following: severity of headaches, level of depression, degree of personal mobility, self-perceived status, effectiveness of a treatment, physical health, emotional health, impact of asthma, job satisfaction, opinion polling, personality test, customer satisfaction and general overall health (Ware; pg. 12, Col. 1-3; pg. 13, col. 1-2).

18. Claims 18-23, 26-28, and 31-34 repeat the limitations of claims 1-6, 9-10, and 14-15 and 17 and the reasons for rejection are incorporated herein.

19. Claim 25 repeats the limitations of claim 8 and the reasons for rejection are incorporated herein.

20. Claim 30 repeats the limitations of claim 13 and the reasons for rejection are incorporated herein.

21. Claims 35-40 repeat the limitations of claims 1, 6, 17, and 18 and the reasons for rejection are incorporated herein.

22. As per claim 41, Ware does not expressly teach wherein at least two domains are selected to be assessed.

However, these features are well known in the art as evidenced by Lewis. IN particular, Lewis teaches both random and adaptive testlet selection are well known in the art (Lewis; Col. 6, "Random vs. Optimum Selection"). Lewis teaches that the method of assigning variable threshold variables to particular testlets. It would have been obvious to add these features to the teachings of Ware with the motivation of balancing the goals of classification accuracy and test efficiency (Lewis; Col. 3, lines 25-31).

23. Claims 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ware et al. (Ware, Jr., John E., Jakob Bjorner, and Mark Kosinski, Dynamic Health Assessments: The Search for More Practical and More Precise Outcomes Measures, The Quality of Life Newsletter, January 1999-April 1999), in view of Bair (6,067,523).

24. As per claims 42-45, Bair discloses:

(a) administering the test before a variable is introduced, wherein said variable includes a pharmaceutical such as Zoloft or Xanax, interventions or therapies (Fig. 1, 29-31, 27B, col. 12 lines 5-55, col. 14 line 43 to col. 15 line 14);

(b) readministering the questionnaire after the variable is introduced (Fig. 1, 16, 29-31, 27B, col. 6 lines 11-21, col. 12 lines 5-55, col. 14 line 43 to col. 15 line 14, col. 15 lines 15-51); and

25. (c) comparing resultant data obtained from each separate administration of said test, wherein said resultant data is indicative of efficacy (see "patient satisfaction and assessing treatment in order to gauge the effect of the treatment upon the behavioral problem) or impact of the introduction of said variable on said health status or health care of said patient (Abstract; Fig. 29-31, 27B, col. 12 lines 5-55, col. 14 line 43 to col. 15 line 14, col. 15 lines 15-51).

The motivation for including the features of Bair within the method and system of Ware being to assess treatment and patient satisfaction (Bair; col. 15 lines 20-30).

Response to Arguments

26. Applicant's arguments in the 11/05/07 Response have been considered but are not persuasive.

(A) Applicant first argues that Ware in view of Lewis does not teach "varying a threshold as a function of said estimated score; and dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside said threshold." Examiner disagrees. Examiner has elaborated in the rejection above the sections of Ware that read upon this limitation. Examiner notes that the "precision standard" described in Ware reads upon a "threshold." Lewis further teaches the concept of "varying thresholds" in adaptive mastery tests.

Lewis teaches the concept of varying a threshold as a function of a score with testlets (Lewis Col. 9, lines 5-10). Testlets are defined as a blocks of items. Lewis, Table 2 teaches that a threshold (Θ_n to Θ_m) varies as a function of the score of a testlet. Based upon the score the examinee is moves on to the next stage (reads upon "dynamically modifying said test...") In other words, an examinee will not be given another testlet unless the score does not fall within the "true mastery status" or "threshold."

Applicant argues on pg. 11 of the 11/05/07 Response that Lewis actually teaches away from *adaptive* testing methods. Examiner disagrees. Although the random

testlet method is a preferred embodiment, Lewis clearly states that both random and adaptive selection can be incorporated into a testlet methodology (Lewis; Col. 8, lines 55-60).

(B) Applicant also argues that Lewis' solution for achieving its results is entirely opposite as proposed by the Applicant's claims. According to MPEP § 2106, USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim should not be read into the claim. *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003). Thus, Applicant focuses on mimicking the evaluation process performed by a professional health care provider but this not recited in the claims and given no patentable weight. The mere fact that Lewis deals with master testing in an educational context does not preclude it from reading upon Applicant's claims as they are given their broadest reasonable interpretation.

(C) In response to Applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5

USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case it is sufficient motivation to balance classification accuracy and test efficiency. In other words, classification accuracy and test efficiency are improved if the right questions quantity and quality of questions are administered in an exam.

In addition, as discussed in the *KSR International Co. v. Teleflex Inc. et al.*, 127 S.Ct 1727 (2007), "[o]ften, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) ('[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness'). As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ" (emphasis added). Therefore, although Lewis does not expressly deal with mimicking the evaluation process of a health care provider Lewis still is relevant as it deals with the related art of testing and self-assessments.

Conclusion

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Linh-Giang Le whose telephone number is 571-272-8207. The examiner can normally be reached on 8 AM - 5PM, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MLL/
Examiner, Art Unit 3626

/C. Luke Gilligan/
Primary Examiner, Art Unit 3626